

REMARKS

Claims 1-17, 19-28, and 30-32 are pending in the present application. In the Final Office Action mailed July 12, 2010, the Examiner rejected claims 1 and 4-16 under 35 U.S.C. §103(a) as being unpatentable over Atalar et al. (USP 6,628,980) (hereinafter “Atalar”) in view of Karmarkar et al. (US Pub. 2004/0046557) (hereinafter “Karmarkar”). The Examiner next rejected claims 2 and 3 under 35 U.S.C. §103(a) as being unpatentable over Atalar in view of Karmarkar as applied to claim 1, and further in view of Nevo (USP 6,516,213). Claims 26-28 and 30-32 were rejected under 35 U.S.C. §103(a) as being unpatentable over Atalar in view of Karmarkar and Nevo. Claims 17, 19-21, and 23-25 were rejected under 35 U.S.C. §103(a) as being unpatentable over Gupta et al. (USP 6,292,683) in view of Atalar and Nevo. Claim 22 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gupta et al. in view of Atalar and Nevo as applied to claim 21, and further in view of Karmarkar.

Premature Finality of Office Action

In the Office Action dated July 12, 2010, which the Examiner made Final, the Examiner applied Karmarkar as a reference for the first time in support of the rejection of claims 1, 4-16, 26-28, and 30-32. However, no substantive amendments were made to claims 1, 4-16, 26-28, or 30-32 in the Response filed April 21, 2010. Instead, claims 1 and 26 were merely amended to correct minor typographical errors. Specifically, in claim 1 “a plurality RF coils” was amended to “a plurality of RF coils” and in claim 26 a semi-colon was inserted at the end of line 8. As such, the July 12, 2010 Office Action includes a rejection premised on newly cited art that was not necessitated by Applicant’s amendment of the claims. Therefore, the Finality of the Office Action dated July 12, 2010 is premature, and the Office Action should be treated as Non-Final.

Rejection under 35 U.S.C. §103(a) over Atalar in view of Karmarkar

The Examiner rejected claims 1 and 4-16 under 35 U.S.C. §103(a) as unpatentable over Atalar in view of Karmarkar et al. The Examiner stated that “Atalar discloses as well known that loop imaging coils provide near field imaging with increased sensitivity distributed across their length (col. 17, II. 1-15).” *Final Office Action*, pg. 4. According to the Examiner, “It is within reason that one of ordinary skill in the art would interpret the gap formed between the plurality of expanded RF coils and the housing to be met by the expanded loop coils of Atalar.” *Id.* In the alternative the Examiner stated:

However, if it is interpreted that Atalar does not expressly teach that the RF coils attachment means to the housing forms a gap, there is nothing in the disclosure to show why the multiple expandable coils of Atalar is not an obvious variant of the present application's gap formed between the RF coils and housing, because both Atalar and the present invention are concerned with achieving the same function of increasing RF sensitivity away from the probe.

Id.

Regarding Karmarkar et al, the Examiner stated that Karmarkar teaches the following: “an expandable basket similar to that disclosed by Atalar (Figs. 6A-D),” “that each expandable arm comprises a plurality of electrodes (0069),” “that the electrodes disposed on the arm may be glued or bonded (0070),” and “that miniature loop coils may be placed adjacent to the one or more electrodes attached to the radially expandable housing (0070).” *Id.* According to the Examiner, it would have been obvious to modify “the expandable housing and imaging coils of Atalar in view of the attachment means for an RF coil to an expandable housing of Karmarkar.” *Id.* The Examiner further stated that the motivation to modify “would be to recognize that Atalar's contribution to the art and to utilize any known RF coil and attachment means such that the variety of imaging coils as suggested by Atalar may be attached to the expandable housing.”

Id.

In the “Response to Arguments” section of the Office Action, the Examiner stated that “[i]t appears that it is Applicant's position that the limitation calling for an attachment means of an RF coil to a medical device differentiates the present invention from the prior art.” *Id.* According to the Examiner, “Applicant continues to argue that because Atalar does not teach the additional elements that may be called a plurality of RF coils and expandable elements such that a gap is formed between the RF coils and the core, that the present invention is distinct from the prior art.” *Office Action*, pg. 13. The Examiner asserted that “[t]his type of variation has been specifically addressed by the Supreme Court [in KSR].” *Id.*

As set forth in detail below, Applicant respectfully disagrees with the Examiner's statements as well as the Examiner's application of the holding set forth in KSR. The Examiner has improperly stretched the teachings of Atalar in order to reflect that called for in claim 1. Further, the Examiner's combination of references does not teach the structural limitations of claim 1, nor are those structural limitations mere obvious variants of the teachings of Atalar.

Atalar discloses numerous embodiments of an imaging device with an expandable loop imaging coil and sleeve. For example, FIG. 6 includes an expandable loop imaging coil (644) and a tubular member (698) that slides between extended and retracted positions. *See Atalar*, col. 13, lns. 49-53. “When the second tubular member (698) is in its retracted state, the expandable

loop imaging coil (604) is in its expanded state.” *Id.* at col. 13, lns. 55-57. As illustrated in FIG. 6B, “the expandable imaging loop (644) can comprise a core (650) surrounded and encased by an insulator (648). In one embodiment, the insulator (648) comprises polymeric tubing. The core (650) is a pre-shaped superelastic electrically conducting material or metal....” *Id.* at col 13, ln. 65 – col. 14, ln. 3. In another embodiment, Atalar discloses an expandable probe 870 comprising a coil region 804 and a tubular member or sheath 802. *Id.* at FIG. 8A, *see also* col. 16, lns. 12-37. “[T]he coil region (804) may be brought into its expanded state by retracting the tubular member (802) to expose the coil region (804).” *Id.* at col. 16, lns. 28-31. The imaging loop or coil assembly may comprise a pair of coils, as coils (607A/607B) of coil assembly (604) shown in FIG. 6D.

Claim 1 calls for, in part, a self-expanding housing insertable into a subject to be imaged and constructed to permit fluid flow therethrough, a plurality of RF coils attached to the housing, and wherein a gap formed between the plurality of RF coils and the housing is configured to increase RF sensitivity away from the probe.

Atalar does not teach a plurality of RF coils and a self-expanding housing as called for in claim 1. While Atalar may disclose a dual coil assembly (604) in FIG. 6D that comprises coils (607A/607B), Atalar does not teach that coils (607A/607B) are attached to a self-expanding housing as specifically called for in claim 1. In fact, Atalar does not even disclose a self-expanding housing with respect to a multiple coil embodiment. Instead, Atalar merely teaches that coils (607A/607B) transition to their expanded state when second tubular member (698) is retracted. *See Atalar*, col. 14, lns. 30-44. At best, Atalar discloses in FIG. 6B a single coil embodiment wherein the coil comprises a nitinol core (650) and insulator (648).

Atalar further fails to teach an imaging assembly wherein a gap formed between the plurality of RF coils and the housing is configured to increase RF sensitivity away from the probe as called for in claim 1. In the Office Action, the Examiner stated that the “housing comprises nitinol and the gap comprises an insulating material because both achieve the same function of increasing RF sensitivity away from the probe.” *Office Action*, pg. 5. Applicant respectfully disagrees. As set forth above, FIG.6B of Atalar discloses imaging coil (604) that is an expandable imaging coil (644) that comprises two elements: a core (650) that is surrounded and encased by an insulator (648). *See Atalar*, col. 13, ln. 65 – col. 14, ln. 3. In the Office Action, the Examiner relied on the core (650) (i.e., the nitinol) to teach the housing and stated that the insulator (648) formed a gap. However, the core (650) and insulator (648) of Atalar together form the coil (604)/(644). Atalar does not teach additional elements that may be called a plurality

of RF coils that are positioned with respect to the core such that a gap is formed between the plurality of RF coils and the core. In fact, Atalar does not teach that anything is positioned at the outer surface of the insulator (648).

Karmarkar also fails to teach a self-expandable housing and a plurality of RF coils attached to the housing, wherein a gap is formed between the plurality of RF coils and the housing as called for in claim 1. While FIGS. 6A-D of Karmarkar may include an expandable housing and a number of electrodes, Karmarkar does not teach that a gap is formed between the electrodes and the housing to increase RF sensitivity away from a probe. Instead, at best, Karmarkar discloses that an “electrode can be disposed on an arm,” and “electrode may be affixed to an arm,” and an “electrode may be glued or bonded to an arm.” *Karmarkar*, ¶[0070]. As such, what the Examiner relied on as “the attachment means for an RF coil” of Karmarkar is not equivalent to the subject matter called for in claim 1.

Further, the Examiner has not provided proper support for the assertion that “it would be a mere obvious variation of the teachings of Atalar to include attachment means for RF coils on the expandable housing” as allegedly taught by Karmarkar to arrive at that called for in claim 1. *See Office Action*, pg. 15. In fact, as explained in detail above, the probe called for in claim 1 includes clear structural differences between that disclosed in the art of record. Thus, the subject matter of claim 1 is not a “combination of familiar elements,” a “mere substitution of one element for another known in the field,” or a use of a “technique [that] has been used to improve one device.” As such, the Examiner incorrectly applied the Supreme Court’s holding in KSR to support the rejection of claim 1.

Accordingly, the art of record fails to teach a self-expanding housing insertable into a subject to be imaged and constructed to permit fluid flow therethrough, a plurality of RF coils attached to the housing, wherein a gap formed between the plurality of RF coils and the housing is configured to increase RF sensitivity away from the probe, as called for in claim 1. As such, Applicant respectfully requests withdrawal of the rejection of claim 1 and all claims depending therefrom.

Rejection under 35 U.S.C. §103(a) over Gupta et al. in view of Atalar and Nevo

Claim 17 was rejected under 35 U.S.C. §103(a) as being unpatentable over Gupta et al. in view of Atalar and Nevo. In the Office Action, the Examiner relied on Atalar to teach an imaging coil (644) “comprising a plurality of RF coils (607a,607b) that are expandable when tubular member (698) is retracted.” *Office Action*, pg. 8. The Examiner further stated that “Atalar

teaches that the housing comprises a first pair of bars and a second pair of bars in first and second orthogonal planes forming the first and second RF loop coils, comprising a high memory nitinol and insulating material.” *Id.* at pg. 9. According to the Examiner, Atalar teaches that “upon the retraction of the sheath the plurality of RF coils are configured to automatically expand from a compressed position.” *Id.* Applicant respectfully disagrees.

Claim 17 calls for, in part, an intra-cardiac catheter constructed to automatically expand to an expanded position from a compressed position, and a plurality of RF coils connected to the catheter, wherein the intra-cardiac catheter is configured to automatically expand the plurality of RF coils to an expanded position from a compressed position.

FIG. 6D of Atalar, to which the Examiner referred in support of the rejection, illustrates an expandable imaging loop (604) that comprises two imaging loop coils (607A/607B) that “may be nested in their collapsed state in a substantially orthogonal manner similar to that illustrated in FIG. 4A.” *Atalar*, col. 14, lns. 32-35. As discussed in detail with respect to claim 1, Atalar does not teach that coils (607A/607B) are attached to a housing. Likewise, Atalar does not teach that coils (607A/607B) are connected to an intra-cardiac catheter or any other structure that is configured to automatically expand to an expanded position from a compressed position and is configured to automatically expand the plurality of RF coils to an expanded position from a compressed position as called for in claim 17. That is, Atalar does not teach or suggest a structure that itself expands and that causes the expansion of a plurality of RF coils that are connected to the structure. While Atalar may disclose a coil assembly comprising a core (650) and insulator (648), Atalar teaches that the core and insulator together form the coil. That is, Atalar does not teach additional elements that may be called a plurality of RF coils connected to the core.

Gupta et al. and Nevo also fail to teach or suggest the catheter/RF coil arrangement called for in claim 17. Accordingly, a combination of the art of record likewise fails to teach or suggest the subject matter as claimed. Thus, Applicant respectfully requests the withdrawal of the rejection of claim 17 under 35 U.S.C. §103(a), along with all claims depending therefrom.

Rejection under 35 U.S.C. §103(a) over Atalar in view of Nevo et al.

The Examiner rejected claim 26 under 35 U.S.C. §103(a) as being unpatentable over Atalar in view of Karmarkar and Nevo et al., stating that “[t]he expandable imaging device of Atalar in view [sic] Karmarkar teaches all the limitations of the claimed invention, as noted above.” *Id.* at pg. 6. The Examiner admitted that “Atalar in view of Karmarkar does not

expressly teach that a tracking coil is configured to transmit tracking signals for gating data acquisition” and “Atalar in view of Karmarkar also does not expressly teach that the device is an intra-cardiac device.” *Id.* at pgs. 6-7. Applicant respectfully disagrees.

Claim 26 calls for, in part, a method comprising inserting an intra-cardiac MR imaging device into a sheath configured for insertion into an imaging subject to be scanned, the imaging device comprising an MR tracking coil and comprising a pair of RF coils attached to an auto-expandable former, positioning the imaging device within the imaging subject to be scanned, and retracting the sheath to allow the former to automatically expand the pair of RF coils to an expanded position.

As discussed in detail above, neither Atalar, Karmarkar, nor a combination thereof teaches a pair of RF coils attached to a self-expanding structure that itself expands and causes the pair of RF coils to expand. Instead, at best, FIG. 6D of Atalar illustrates an imaging loop (604) comprising a pair of coils (607A/607B) configured to rotate to an expanded position when a tubular member (698) is retracted. *See Atalar*, col. 14, lns. 30-45. Atalar does not teach that coils (607A/607B) are attached to an auto-expandable former as called for in claim 26. Likewise, Atalar does not teach retracting a sheath to allow a former to automatically expand a pair of RF coils to an expanded position. While, Karmarkar may disclose an expandable arm 38 having a number of electrodes attached to it, Karmarkar does not teach RF coils attached to expandable arm much less teach that expandable arm causes a pair of RF coils to expand.

Nevo et al., which relates to determining instantaneous location of an object, likewise fails to teach the steps of inserting, positioning, and retracting as called for in claim 26. Accordingly, the Examiner’s combination of references fails to teach the limitations of claim 26. Therefore, Applicant respectfully requests withdrawal of the rejection of claim 26 and all claims depending therefrom.

Therefore, in light of at least the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-17, 19-28, and 30-32.

Applicant appreciates the Examiner's consideration of these Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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General Authorization and Extension of Time

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 07-0845. Should no proper payment be enclosed herewith, as by credit card authorization being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 07-0845. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extensions under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 07-0845. Please consider this a general authorization to charge any fee that is due in this case, if not otherwise timely paid, to Deposit Account No. 07-0845.

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